

REMARKS

Status of Claims

Claims 16 and 29 have been amended to obviate the rejections under 35 U.S.C. §102(b). No other claim has been added, amended, or canceled, and no new matter has been added. Also, no new issues have been raised that would require further consideration and/or search. Upon entry of the claim amendments, claims 1-13, 16-21, 24-26, 29, and 31 will remain in the application.

Claim Rejections – 35 U.S.C. §102(b)

Claims 16-21, 26, and 29 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by WO 01/62336 (“Brighton”) or US Patent No. 4,600,010 (“Dugot”). These rejections are traversed.

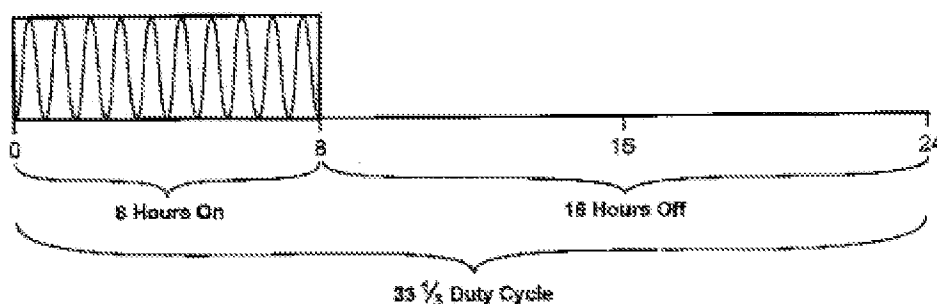
In the Final Rejection, the examiner alleges that the devices of Brighton and Dugot can output the recited signal. At least with respect to Dugot, Applicant disagrees. Independent claims 16 and 29 have been amended to specify that the signal source controls and varies “duration of time of application of said at least one specific and selective signal for a predetermined duration of time from approximately ½ hour to 24 hours per 24 hour period” and controls and varies “the duty cycle of said at least one specific and selective signal from approximately 10%-100%” so as to selectively up-regulate the gene expression of BMP-4, BMP-5, BMP-6, and/or BMP-7 in the targeted tissue as measured by mRNA as a result of application of the specific and selective field in the targeted tissue. The device taught by Dugot cannot perform, and does not teach, these features.

In particular, Dugot does not provide a signal source with means for controlling and varying the duty cycle of the at least one specific and selective signal applied to the field generating device “from approximately 10% to 100% so as to selectively up-regulate gene expression of BMP-2 (or BMP-4, BMP-5, BMP-6, and/or BMP-7) in the target tissue as measured by mRNA as a result of application of the specific and selective field in the targeted tissue” as claimed. This is distinct from turning on and off the device as taught by Dugot, which relates to the duration of application of the signal or the interval between applications. In other

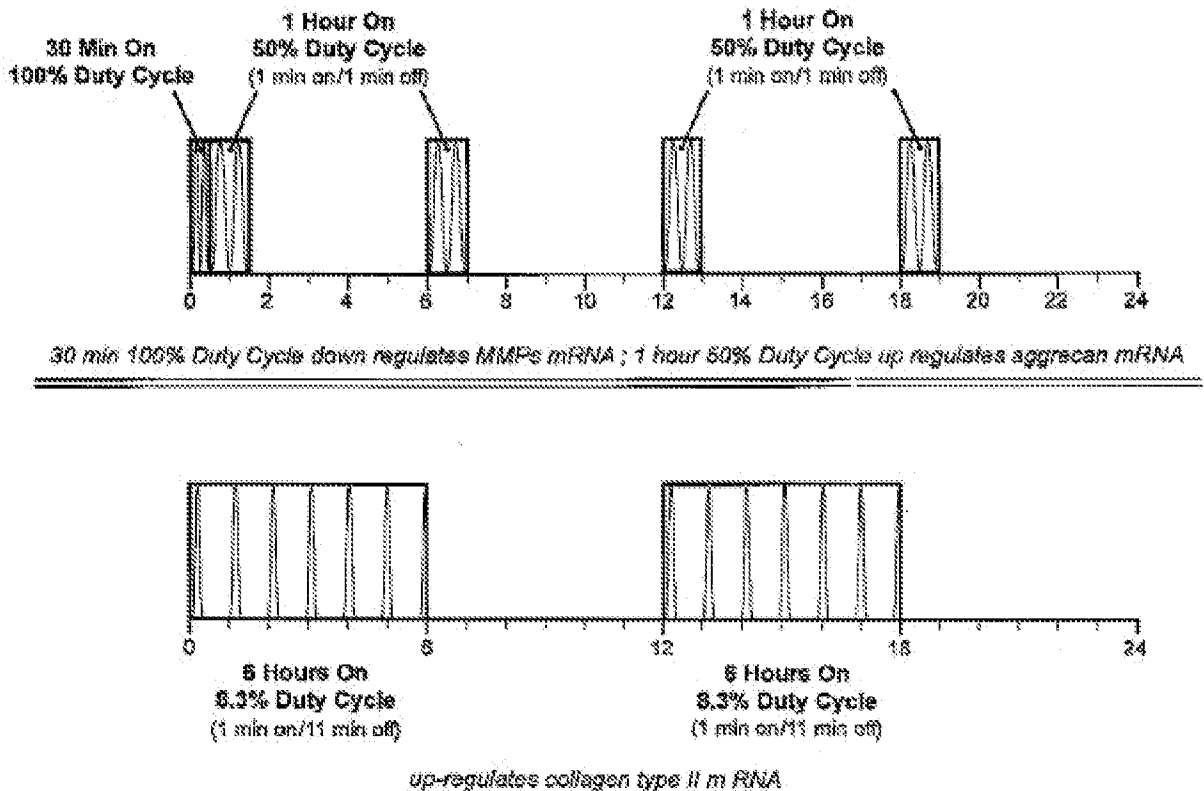
words, Dugot teaches varying the duration of application of the signal by turning the device on and off but does not teach varying the duty cycle as claimed. Also, Dugot did not teach a “specific and selective signal” as claimed and Dugot does not teach means for varying the duty cycle of such signal to “selectively up-regulate” gene expression of a BMP gene in the injured or diseased tissue as claimed. Absent such teachings, the rejections over Dugot cannot be maintained. Withdrawal of the rejections of claims 16-21, 26, and 29 as being anticipated by Dugot is solicited.

The examiner is reminded that Dugot discloses a body stimulator apparatus having a signal generator that supplies a periodically varying treatment signal of ultrasonic frequency (e.g., 60 KHz) and given voltage and current to electrodes on a patient. As noted at column 3, lines 8-17, the apparatus may be set for continuous operation or for intermittent operation at a selected on-off timing rate. For example, a “duty cycle” of eight hours on, sixteen hours off, or a “duty cycle” of two hours on, twelve hours off, and the like is disclosed. Applicant notes that the use of “duty cycle” by Dugot corresponds to the “duration of time of application” of the specific and selective signal (see Figure 1 of the present application) as opposed to the use of “duty cycle” (see Figure 4 of the present application) in claim 16 which relates to the on/off intervals during the time of application of the signal. This distinction is also illustrated in the Figures below (the examples illustrate duty cycles for MMP, aggrecan and collagen but the same principles apply to BMP):

Dugot's Patent: "On/Off" Duty Cycle



Brighton's Patent: "On" Duty Cycles



Unlike the claimed apparatus, Dugot does not generate a "specific and selective signal" or a "specific and selective field" and certainly nowhere discloses that the generated field up-regulates gene expression of BMP as claimed. All Dugot suggests is either applying the signal continuously or intermittently; Dugot says nothing of varying characteristics of the signal or field (such as duty cycle) in order to achieve a particular result (*e.g.*, a field having an amplitude of about 2 to 40 mV/cm in the targeted tissue that is specific and selective for the up-regulation of the gene expression of bone morphogenetic protein-2 (BMP-2) in the targeted tissue). Dugot's suggestion of applying a 60 KHz signal to an electrode on the patient and to continuously or intermittently apply the signal to "treat" the living tissue falls far short of anticipating or rendering obvious the claimed invention. Certainly, Dugot do not "inherently" generate the claimed "specific and selective signal" with the claimed duty cycle and duration characteristics.

Also, “selectively regulating” gene expression as claimed clearly is not “inherent” in the teachings of Dugot. Dugot provides no teachings of varying the signal characteristics to achieve different results, certainly not different gene expressions of BMP as claimed. Withdrawal of the rejection of claims 16-21, 26, and 29 as being anticipated by Dugot is thus solicited.

With respect to Brighton (WO 01/62336), the examiner is asked to note that the present application claims priority from the application upon which that publication is based, thereby obviating the rejection over Brighton. Withdrawal of the rejection of claims 16-21, 26, and 29 as being anticipated by Brighton is thus appropriate and is solicited.

Allowed Claims

Applicant again appreciates the examiner’s indication that claims 1-13, 24, 25, and 31 are allowed. For the reasons noted herein, all pending claims are now believed to be allowable.

CONCLUSION

Applicant respectfully submits that claims 1-13, 16-21, 24-26, 29, and 31 as amended are in condition for allowance. Early and favorable consideration is earnestly solicited. Moreover, if the Examiner does not find the present response sufficient to overcome any of the outstanding rejections, the Examiner is encouraged to contact the undersigned attorney to discuss suitable claim language for overcoming the rejection.

The Commissioner is also hereby authorized to charge any fee deficiency, charge any additional fees, or credit any overpayment of fees, associated with this application in connection with this filing, or any future filing, submitted to the U.S. Patent and Trademark Office during the pendency of this application, to Deposit Account No. 23-3050.

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